Organization

Overview

The State of Kansas has established a program of surveillance for the OraQuick ® Rapid HIV-1 antibody test. This program will take testing to the populations at risk by integrating and linking Voluntary Counseling and Testing (VCT) with HIV/STD prevention and case management activities. The goal of the Kansas Rapid HIV Program Quality System (QS) is to provide excellence in clinical testing and performance through continuously monitoring and evaluating the quality of testing performance. Quality assurance monitors are dispersed throughout the QS program. Ongoing review and updates of the program will provide intervention, when appropriate, to improve testing quality and be responsive to the needs of the community and public health programs.

Federal Regulations

The Kansas Rapid HIV Laboratory has applied for and received a CLIA certificate (17Dxxxxxx) for the performance of waived test procedures. This certificate will be maintained for the duration of the program. Any certificate changes, such as laboratory director, will be reported to the CLIA Program office in Topeka within 30 days. All laboratory testing will be in compliance with CLIA '88 requirements for waived testing. Enhanced program requirements, in excess of CLIA standards, will ensure quality of testing.

Personnel

Medical Officer

This individual will meet the following requirements:

- Physician (MD, DO) with current Kansas license

Duties:

- Provide consultation as to the appropriateness of the testing ordered and interpretation of test results, and
- Ensure that consultation is available to the laboratory's clients on matters relating to quality of the test results reported and their interpretation concerning specific patient conditions

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Laboratory Director

This individual will meet the following requirements:

- Doctorate, Master's, or Bachelor's degree in biological or laboratory science
- Two or more years of supervising/directing non-waived laboratory testing

Duties:

- Provide overall operation and administration of the laboratory
- Ensure that the physical facility and environmental conditions are appropriate for testing and provide a safe working environment
- Ensure that all individuals involved in the testing process have the required credentials and training
- Ensure that all assigned responsibilities are performed
- Review and approve all procedures prior to implementation
- Be accessible to provide onsite, telephone or electronic consultation
- Ensure that test systems provide quality service in all aspects of the testing: pre-analytical, analytical and post-analytical
- Ensure that test records include all pertinent information required for interpretation
- Conduct biannual state meetings and/or regional meetings where program personnel will discuss laboratory issues

Technical Consultant

This individual will meet the following requirements:

- Doctorate, Master's, or Bachelor's degree in biological or laboratory science
- Two or more years of supervising/directing non-waived laboratory testing

Duties:

- Ensure the verification and validation of the OraQuick® Rapid HIV test system and establish test performance characteristics
- Ensure enrollment and participation in proficiency testing programs
- Ensure that quality control and quality assurance programs are established and maintained
- Ensure that adequate levels of analytical performance are maintained
- Ensure that patient test results are not reported when test system specifications are not met
- Ensure corrective action is taken when appropriate and is sufficient to resolve system problems
- Train testing personnel to correctly perform the OraQuick® rapid HIV test
- Evaluate and document the performance of individuals responsible for testing at least semiannually during the first year the individual tests patient specimens, thereafter, annually
- Evaluate the competency of testing personnel and assure competency by direct observation, review of worksheets, review of proficiency testing and assessment of test performance through previously analyzed specimens
- Participate in regional program meetings.

Educator

This individual will meet the following requirements:

- Doctorate, Master's or Bachelors in chemical, biological or laboratory science

Duties:

- Train testing personnel to correctly perform the OraQuick® rapid HIV test
- Evaluate and document the performance of individuals responsible for testing at least semiannually during the first year the individual tests patient specimens, thereafter, annually
- Evaluate the competency of testing personnel and assure competency by direct observation, review of worksheets,

review of proficiency testing, and assessment of test performance through previously analyzed specimens
- Provide on-site visits to appraise program compliance and assess need for updates
- Participate in regional program meetings

Note: Many of the duties and responsibilities of the technical consultant and educator may overlap. These dual duties will be coordinated between personnel filling these positions, with the approval of the laboratory director.

Testing Personnel This individual will meet the following requirements:

- Minimum of a high school diploma or equivalent
- Possess good communication skills
- Possess good decision making skills
- Must pass training process
- Must demonstrate continued competency in test performance

Duties:

- Perform only tests authorized by the director
- Follows the laboratory's safety and blood-borne pathogen protocols
- Follows the laboratory's procedures for specimen handling, processing, result reporting, and record maintenance
- Performs internal and external audits and proficiency testing as required
- Adheres to the laboratory's quality control policies
- Follows the laboratory's established corrective action policies
- Identifies all problems that adversely affect test performance and documents all corrective action taken

***** The credentials of each testing personnel must be available on-site. Credentials of all other personnel will be on file in the Kansas Rapid HIV program office and available upon request.**

Training

Training, crucial to test performance, is required by the OraQuick® test kit. Prior to client testing, each individual must complete the following:

- Watch the blood-borne pathogen video
- Read the OSHA blood-borne pathogen protocol
- Successfully pass the blood-borne pathogen quiz
- Watch the OraQuick® training video
- Read the procedure for performance of the OraQuick® rapid HIV test
- Practice performing the test with positive and negative control material
- Practice performing the finger-stick collection procedure
- Know how to document testing and quality control results
- Know when and how to take corrective action
- Successfully pass the training program and be signed off by the trainer
- Sign the training form (see Appendix x) stating that the tester is confident in how to correctly perform the procedure

If additional training needs are identified by either the technical consultant or the educator, these areas will be specified and resolved prior to the individual performing client tests. The training document **must** be signed **both** by the trainer and the tester. **No individual may test client specimens prior to completion of the training process.**

Post-training

Within six months of initial training, each testing personnel must be re-evaluated for ability to correctly perform all aspects of the test process (Appendix x).

Competency

All personnel will be evaluated on an annual basis to ensure the continuation of quality laboratory results. This competency may include, but is not limited to, review of logs, worksheets, quality control records and client test records, direct observation of testing, review of proficiency testing results and interpretation of photographs of previous analyzed client tests (Appendix x).

Facilities, Equipment, and Safety

General

Physical Location

- Facilities are to be maintained in a state of cleanliness, order, and efficiency conductive to productivity and safety.
- Facilities for hand washing will be available either in or immediately adjacent to the laboratory area.
- All areas where reagents are stored and testing is performed will comply with the manufacturer's requirements.
- Refrigerator temperature, room temperature and temperature of the testing area will be monitored on a daily basis. All deviations will elicit immediate corrective action which will be documented on the temperature log sheet. If the temperature can not be brought into the required range, the technical consultant will be notified.

Equipment

Equipment required for each testing site:

- Two to three thermometers, dependant upon the proximity of testing and storage areas. All thermometers used by the laboratory will be calibrated with a certified thermometer (NBS traceable) prior to use and annually thereafter. These results will be documented (Appendix x)
- Timer capable of timing 20 to 60 minutes

Specimen collection supplies will consist of the following:

- Sterile safety lancets
- Disinfectant wipes
- Sterile gauze pads
- Absorbent pads
- Latex and vinyl gloves
- Protective goggles
- Surface disinfectant
- Biohazard disposal device
- Sharps container

Laboratory reagents

- Two boxes of OraQuick® Rapid HIV-1 test kits and two boxes of OraQuick® quality control material will be stored at each testing facility. Ordering of reagents will be on an as needed basis.
- All reagents will be marked with the date received.
- All reagents will be marked with the date opened.

- Since quality control material has a twenty-one day expiration date post opening, the old expiration date will be marked out on the vial and the new expiration date listed.
- All reagent kits must be stored at 2 to 27 °C
- Control kits must be refrigerated at 2 to 8 ° C
- Expired reagents must never be used for clinical testing.
- Components of reagent kits of different lot numbers are not interchangeable.
- Material Safety Data Sheets (MSDS) for all reagents are stored in the safety manual.

Safety

Persons involved in patient testing will have an occupational exposure to blood and will meet the U.S. Department of Labor Occupational Health and Safety Administration (OSHA) standards for boodborne pathogens. The Kansas HIV safety plan includes the following:

- The Exposure Control Plan, including post-exposure evaluation and follow-up to all employees who have had occupational exposure
- Personal protective equipment
- Availability of the hepatitis B vaccine to all employees with occupational exposure
- Training for all employees with occupational exposure
- Site procedures for containment and disposal of biohazard waste in compliance with State and Federal regulations
- MSDS sheets

Testing

Validation

Prior to client testing, the OraQuick® test kit will be challenged by specimens received from the Centers for Disease Control (CDC) Model Performance Evaluation Program (MPEP). These will include specimens that are reactive, weakly reactive and negative. All tests specimens will be performed with 100% accuracy prior to client testing.

Continuous validation of the test method will be performed by the following:

- Extensive training of individuals prior to the performance of client testing,
- Competency evaluations of testing personnel within six months of initial training to insure training effectiveness,
- Competency evaluations of all testing personnel on a yearly basis thereafter,
- Each test will be performed within the manufacturer's required specifications,
- Performance and review of external and internal quality control,
- Performance of unknown specimens (proficiency testing) twice a year,
- Review of participant data summaries from proficiency testing institutes (3 times/year)
    1. www.api-pt.com
    2. www.aab.org
    3. www.cap.org,
- Case by case comparison between screening and confirmatory testing,
- Communication logs to stimulate discussion of testing method, quality control issues and other, and
- Quarterly meetings to discuss and evaluate the overall quality and effectiveness of the program.

Testing – Pre Analytical

Preparing to test

Temperature Test Kit	Each test kit will be stored at room temperature (15° to 27° C). If test kits have been placed in a cooled environment for transport (must be within 2° to 27° C) the kit must be brought to room temperature prior to use. If the temperature falls outside of the required range, immediate action must be taken to correct the temperature, two external controls must be run with the kit, and the technical consultant must be contacted prior to performing client testing. A calibrated thermometer will be placed in the area where the test kits are stored and daily temperature readings will be documented.
Controls	Control kits must be refrigerated at 2° to 8° C. Controls must be brought to room temperature prior to use. A calibrated thermometer will be placed on the same refrigerator shelf as the controls, and daily temperature readings will be documented. Immediate action must be taken if the temperature exceeds the acceptable range.
Testing Area	The temperature in the area where the test will be performed must be within the range of 15° to 27° C. A calibrated thermometer will be placed in the area immediately adjacent to patient testing and the temperature will be read and documented each day of testing. Patient testing will not be performed when the temperature exceeds the acceptable range.
Alternate Sites	If testing is carried out in the field, the temperature of the test and control kits in their portable storage container and the temperature where testing will be performed will be monitored. These temperatures will be documented on the clin testing log sheet.
Inventory	Test kits and controls will not be used beyond their expiration date. Use the kit and control products with the shortest expiration date first.

External Controls

The manufacturer of the OraQuick Rapid HIV-1 test kit has set the following prescribed guidelines for the minimum number of times to run external negative and positive controls:

- By each new operator prior to performing client testing,
- When opening a new test kit lot,
- Whenever a new shipment of test kits is received (even if it is the same lot number in use),
- If the temperature of the test storage area falls outside of 2°-27° C, and
- If the temperature of the testing area falls outside of 15°-27° C.

Additional requirements set by the Kansas Rapid HIV Program are:

- Daily, for any testing site performing ten or more client tests per day, and
- For sites performing less than ten client per day, external controls will be run at least monthly.

Test Area Setup

Follow the OraQuick® test procedure for setting up the workspace. Label the test device with one of the two unique patient identifiers. Do not place a label over the two holes on the back of the test device as this can cause an invalid result.

Subject Information

OraSure Technologies, Inc. provides a "Subject Information" pamphlet that **must** be given to each person tested **prior** to performing the HIV rapid test. It will be documented on the client test record that this pamphlet has been given to the client.

Testing – Analytical

Testing the patient

Collection	Laboratory staff will follow the written procedure for finger-stick specimen collection.
Test and Interpretation	All client testing will be performed in accordance with the manufacturer's specifications and the written procedure. Results can be one of the following: • *Nonreactive* (negative) • *Reactive* (preliminary positive) • *Invalid* (the test result is inconclusive and cannot be interpreted)
Evaluating the Internal Control	Each OraQuick® test device contains a built-in or internal control. When an appropriate line develops at the center of the "C" location on the device, the client's specimen has been correctly loaded and traveled through the test strip. Failure to observe this line results in an *invalid* test and the client test result **cannot** be reported. The test should be repeated with a new finger-stick and kit components.
Troubleshooting	If a second invalid test result is obtained during the performance of client testing, external controls will be run on the kit. If the same test kit yields repeated invalid results, the test kit should be sealed with tape, labeled "Do Not Use" and stored in an alternate location for evaluation by the technical consultant.
Biohazard Waste	All specimens and materials contacting specimens must be handled as if they are capable of transmitting an infectious organism. Lancets used for collection of the blood specimen must be disposed of in biohazard sharps containers.

Testing - Post-Analytical

After Testing

Patient testing log

Each client will be designated by two unique identifiers. One will be the first letter of the client's first name and the first letter of the client's last name followed by the numeric date of birth (month, day, year). The second identifier is the client's name. The following information will be entered into the client test log:

- The client identifier (name)
- The date and time of client testing
- The initials of the testing personnel
- The interpretation of the test
- The observation of the internal procedural control
- Confirmatory testing information, if indicated

In order to track each test performed, the lot number and expiration date of each test kit utilized will be recorded on the client testing log. When a new kit lot number is opened, a new client test log will be started.

Reporting results to the patient

Laboratory test results will be reported to the client in verbal form.

Referral for Confirmatory Testing

Whenever the OraQuick® test result is reactive (preliminary positive), a confirmatory test must be performed to confirm that the person being tested is infected with HIV. Confirmatory testing will be referred as follows:

- All blood confirmatory testing will be sent to the Kansas Department of Health and Environmental Laboratories, Forbes Field, Building 740, Topeka, Kansas (CLIA # 17D0xxxxxx). Specimen requirements including collection, labeling, storage, and shipment to the testing facility is provided in the State of Kansas Reference Manual (Appendix x)
- All oral fluid confirmatory testing will be sent to the Communicable Disease Detection (CDD) laboratory in Texas (CLIA # xxxxxxxxxx).

- A specimen transfer log will be maintained to ensure that all tests sent on for confirmation receive prompt attention. The type of specimen submitted along with the results of the confirmatory test will

	be documented on the client test log (Appendix X). Results will be reviewed by program staff and any discrepancies between the preliminary result and the confirmation result will be investigated.

All OraQuick® reactive (preliminary positive) results must be followed up with an immunofluorescent assay (IFA) on whole blood or by western blot on oral fluid.

Follow up testing for negative confirmatory testing	In the event of a negative confirmatory test, the technical consultant must be notified immediately and follow-up action taken to identify any source of error in order to resolve the immediate situation and prevent future problems. Whenever possible, the client will be asked to return to the facility for repeat screening and confirmatory testing.
Follow up testing for indeterminate confirmatory tests	In the rare event that a confirmatory test is considered to be indeterminant, the client will be notified and requested to return for repeat testing in one month.
Confirmatory	Once the confirmatory test results have been found to correlate with the OraQuick® screening results, the client will be notified according to the Kansas HIV program procedure.

Records

Retention

All records pertaining to the Kansas OraQuick® Rapid HIV-1 program will be retained a minimum of five years. Records will be maintained in an environment that will ensure adequate preservation. If a site is utilized temporarily, the Kansas HIV Program will be responsible for sustaining the records at that site or moving the records to another suitable location.

Specifications

All records must comply with the following:

- All client test logs, quality assurance logs, and quality control logs must be legible,
- Client test logs and client test reports must contain the name and address of the testing facility,
- Entries to any log must be understandable to other testing personnel and supervisors,
- Data will be recorded on logs using permanent ink. Pencils and correcting fluid are not permitted. If an error on a log is made, cross out the error with a single line and enter the correct information,
- Unauthorized changes to any procedure, log or alternate record is not permitted, and
- Records for the most recent two years of testing must be retrievable within a reasonable period of time.

Corrective Action

Should a reported error be detected, a Corrective Action Report will be generated (Appendix X). Any telephone communication in connection with the investigation must be documented. A corrected report, labeled "Corrected Report" will be generated and sent to the patient. Both the original report and the corrected report will be maintained. The phrase "Corrected Report" will be highlighted and placed on top and the two reports stapled together.

Confidentiality

All records connected with the Kansas Rapid HIV testing program will be considered confidential and subject to Kansas HIV reporting and confidentiality regulations (K.S. 656002 and 656003).

Assessments – Internal & External

External – Proficiency Testing	Each testing site will be enrolled in an external proficiency testing program. Two unknown specimens will be evaluated twice a year. All individuals involved in patient testing will be participate in performing and evaluating proficiency testing. All proficiency testing specimens will be treated in the same manner as patient testing. Results of proficiency testing will be reviewed by the technical consultant. Any discrepancy between the acceptable answer and the answer obtained will be result in the generation of a proficiency testing failure evaluation form (Appendix X).
External - Proficiency Testing Result Review	Proficiency testing results from the OraQuick® test kit will be evaluated in all three yearly events for the following proficiency testing providers: • College of American Pathologists (CAP) • American Proficiency Institute (API) • American Association of Bioanalysists (AAB) Evaluation of the performance of the test kit in each event will be discussed at management meetings. Evidence from this data indicating that the kit is unable to perform accurately will result in the immediate suspension of rapid HIV testing until further evaluation can be performed.
External - Result Comparison	Each reactive result (preliminary positive) will be compared with the results of the confirmatory test. Discrepancies will be evaluated and resolved whenever possible.
External - Literature Review	All performance evaluation studies published by the Centers for Disease Control (CDC) and other relevant, valid publications comparing the methodology of the OraQuick® Rapid HIV-1 test with alternate methods will be reviewed.

Internal - Personnel Assessment	All personnel will be evaluated within six months of training to ensure quality of testing and annually thereafter. Training issues will be identified and **r**esolved**.**
Internal - Record Review	All of the following records will be reviewed at the time of the site visit by the technical consultant (at least quarterly): • Training, when applicable, • Competency, when applicable, • Quality Control, both external and internal, • Client test records, • Communication logs, • Maintenance logs, and • Temperature logs Review of all records will be documented.

Process Improvement

The program management of the Kansas Rapid HIV Test Program will demonstrate active support of the goals and objectives of quality systems. Program managers and supervisors will review, at least on a quarterly basis, quality assurance reports for each testing site, evaluate the data, and prepare conclusions. All testing sites must comply with all parts of the Kansas Rapid HIV Testing Program. Continued validation of the test method, in coordination with management review will provide a high degree of assurance that the OraQuick® Rapid HIV-1 Test Method meets specifications of accuracy, sensitivity and specificity.

References:

1. OraQuick® Rapid HIV-1 Antibody Test package insert. OraSure Technologies,Inc., Bethlehem, PA 18015, 2003.
2. Occupational Safety and Health Administration regulations, 29 CFR Part 1910.
3. Centers for Disease Control and Prevention, Quality Assurance Guidelines for Testing Using the OraQuick® Rapid HIV-1 Antibody Test.
4. Michigan State Laboratory Quality Assurance Manual.
5. Code of federal regulations. Title 42 CFR Parts 493 to end. Washington, DC: US Government Printing office, 1998 (revised).
6. American Association of Blood Banks Technical Manual, 13th Edition, 8101 Glenbrook Road, Bethesda, Maryland 20814.